

Individualized vs Standard Blood Pressure Control During Thrombectomy for Ischemic Stroke

The DETERMINE Randomized Clinical Trial

Benjamin Maier,^{1,2,3,4,5} Benjamin Gory,^{6,7} Russell Chabanne,⁸ Benoit Tavernier,^{9,10} Alice Jacquens,^{11,12} Baptiste Balanca,^{13,14} Maxime Pommier,¹⁵ Morgan Le Guen,¹⁶ Laurie-Anne Thion,¹⁷ Simon Clariot,¹⁷ Bertrand Lapergue,¹⁸ Adrien Guyot,⁸ Omer F. Eker,¹⁹ Lionel Bapteste,^{13,14} Jean Marc Olivot,²⁰ Lionel Calviere,²⁰ Gabriela Julean,^{9,10} Pauline Bourst,²¹ Gérard Audibert,²¹ Vincent Degos,^{11,12} Julie Dupont^{11,12} et al.

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Correspondence

Prof. Maier
bmaier@for.paris

Abstract

Background and Objectives

Current recommended blood pressure (BP) targets during mechanical thrombectomy (MT) rely on a one-size-fits-all approach aiming at preventing hypertension. The efficacy and safety of an individualized BP control during thrombectomy for ischemic stroke has not been well studied. We aimed to evaluate whether an individualized BP control during MT could improve functional outcome at 90 days.

Methods

We conducted a multicenter, open-label, blinded-endpoint, randomized clinical trial at 8 academic comprehensive stroke centers in France. Adult patients with an acute ischemic stroke due to an anterior large vessel occlusion and an indication for MT were eligible. Recruitment was performed between March 10, 2021, and September 18, 2023. Patients were randomly assigned (1:1) to an individualized BP group during MT (where the mean arterial pressure [MAP] was maintained within 10% of the first MAP measured before MT) or a control BP group (systolic BP maintained within 140 and 180 mm Hg). The primary outcome was favorable functional outcome, defined as a modified Rankin Scale score between 0 and 2 at 90 days. Safety outcomes included symptomatic intracranial hemorrhages at 24 hours and mortality at 90 days.

Results

Overall, 433 patients (median age, 69.3 years, 228 females [52.8%]) were assigned to an individualized BP group (n = 215) or the control BP group (n = 218); one was excluded because of consent withdrawal. No significant differences in mean BP levels or BP variability were observed between groups during the procedure. Favorable functional outcome at 90 days was observed in 94 patients (44.2%) in the individualized BP group and 106 patients (48.8%) in the control group (adjusted odds ratio, 0.82; 95% CI 0.54–1.24; *p* = 0.34). Mortality from any cause at 90 days was not significantly different between groups (18.8% in the individualized BP group vs 16.4% in the control BP group; adjusted odds ratio, 1.19; 95% CI 0.70–2.03). Rates of symptomatic intracranial hemorrhages were not different between the 2 groups.

Discussion

In patients with acute ischemic stroke due to an anterior large vessel occlusion, an individualized BP management during MT did not increase rates of favorable functional outcome at 90 days compared with a standard BP management.

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Glossary

AIS = acute ischemic stroke; **BP** = blood pressure; **FO** = functional outcome; **IQR** = interquartile ranges; **LVO** = large vessel occlusion; **MAP** = mean arterial pressure; **mRS** = modified Rankin Scale; **MT** = mechanical thrombectomy; **mTICI** = modified Treatment in Cerebral Ischemia; **NIHSS** = National Institutes of Health Stroke Scale; **OR** = odds ratio; **SBP** = stabilize systolic BP.

Trial Registration Information

ClinicalTrials.gov, DETERMINE, number NCT04352296.

Classification of Evidence

This study provides Class II evidence that in patients undergoing mechanical thrombectomy for stroke due to anterior large vessel occlusion, functional outcomes at 90 days were similar with individualized BP management and standard BP management.

Introduction

Mechanical thrombectomy (MT) is the standard treatment for acute ischemic stroke (AIS) due to an anterior large vessel occlusion (LVO).^{1,2} Although reperfusion rates now exceed 90%,³ clinical outcomes remain suboptimal, with nearly half of treated patients experiencing poor outcome at 90 days.⁴ To address this situation, efforts have been made to optimize periprocedural management. Several observational studies have identified strong associations between hypotension and blood pressure (BP) variability during MT with increased infarct growth, worse outcome at 90 days, and higher mortality.⁵⁻⁹ These hypotensive episodes and BP fluctuation during MT are common,^{5,6,8} often attributed to the anesthetic agents used to perform MT under conscious sedation or general anesthesia. It is important that their effect on functional outcome (FO) seems to vary among patients and may depend on individual factors, such as the collateral status or the anatomy of the Circle of Willis.^{10,11} However, the optimal BP management during MT has not been yet defined. Current guidelines largely follow a “one-size-fits-all” approach, by applying a uniform BP threshold (i.e., <180/105 mm Hg) to all patients during and after MT.^{2,12} Unfortunately, this strategy led to several negative trials regarding BP management after MT.¹³⁻¹⁶ In other fields, such as major surgery, the feasibility and efficacy of an individualized BP management has already been demonstrated using diluted norepinephrine to stabilize systolic BP (SBP) within narrow limits.¹⁷ In the stroke setting, the INDIVIDUATE trial evaluated an individualized SBP management during MT in a monocentric randomized design but failed to show superiority over standard BP management.¹⁸ Mean arterial pressure (MAP) may be more relevant than SBP, given its association with cerebral perfusion pressure and intracranial pressure. Several studies have indeed suggested that controlling MAP within narrow limits during MT might improve FO at 90 days.^{8,19} However, the IDEAL trial, a pilot monocentric randomized trial evaluating an individualized MAP strategy during MT under general anesthesia, also failed to demonstrate feasibility or benefit.²⁰

In this context, we conducted the Individualized vs Standard Blood Pressure Management During Mechanical Thrombectomy (DETERMINE) trial to assess the efficacy and safety of an individualized BP management strategy during MT, in which MAP was maintained within 10% of the first MAP measured before MT, compared with a standard BP strategy (target SBP between 140 and 180 mm Hg) in AIS patients with an anterior LVO.

Methods

Standard Protocol Approvals, Registrations, and Patient Consents

The DETERMINE trial was an investigator-initiated, multicenter, open-label, randomized clinical trial with blinded outcome assessment, conducted at 8 comprehensive stroke centers in France (listed in eTable 1). Sites were selected for their expertise in anesthesiology, ensuring 24/7 access to the neuroanesthesiology team for each MT procedure. The protocol has been published (eSAP 1)²¹ and was approved by the *Comité de Protection des Personnes Ouest V* on September 29, 2020, by the *Agence Nationale de Sécurité du Médicament et des produits de santé* (ANSM) on July 30, 2020, and by the institutional review board at each participating site. The statistical analysis plan (eSAP 2) was completed on September 18, 2024. The first and last patients were enrolled on March 10, 2021, and September 18, 2023, with database closure on September 25, 2024. The trial was conducted in accordance with the revised Helsinki guidelines. The trial was designed and conducted by an executive committee, who met regularly to oversee the trial and analyze data. An independent data and safety monitoring board was responsible for safety and ethics oversight. An independent clinical-events committee adjudicated all safety outcomes, procedure-related complications, and serious adverse events. All neuroimaging data were centrally assessed by a core laboratory blinded to group assignments. Data management was performed by the Clinical Research Unit at *Hôpital Fondation A. de Rothschild*.

This trial was funded by the French Health Ministry (PHRC, AOR19069) and was registered on ClinicalTrials.gov (NCT04352296).

Eligibility assessments were conducted by the treating physician. In accordance with Article L.1122-1-3 of the French Public Health Code, a deferred-consent procedure was used. When possible, patients provided written informed consent before inclusion; otherwise, consent was sought from a legal representative or family member, or inclusion proceeded under emergency provisions. Patients' capacity was reassessed, and written consent for continuation was obtained from the patient as soon as possible, typically within 24–48 hours.

Participants

Patients were eligible for inclusion if they were aged 18 or older, presented with AIS due to an anterior LVO (involving the intracranial segment of the internal carotid artery, M1 or proximal M2 segment of the middle cerebral artery occlusion, A1 segment occlusion of the anterior cerebral artery, or a tandem occlusion), and were eligible for MT according to European and North-American guidelines.^{1,2} Perfusion imaging was therefore not mandatory and not performed in the early time window (<6 hours). Exclusion criteria included intubation or general anesthesia induction before randomization, posterior circulation strokes, and a prestroke-modified Rankin Scale (mRS) score >2. Detailed inclusion and exclusion criteria are provided in eSAP 1.²¹ No eligibility screening log was maintained.

Randomization and Blinding

Patients were randomly assigned before MT in a 1:1 ratio, using a secure Web-based system, to an individualized or a standard BP control group. Randomization used a minimization procedure to balance groups according to key clinical characteristics: age (<70 vs ≥70 years), sedation modality (general anesthesia vs conscious sedation), baseline National Institutes of Health Stroke Scale (NIHSS) score (<17 vs ≥17), use of intravenous thrombolysis, and the center. Patients, investigators, and treating physicians were aware of group assignments, but the primary outcome was assessed by certified neurologists or research nurses blinded to trial-group assignments, and all radiologic endpoints were assessed centrally by a radiologic core laboratory, blinded to trial-group assignments.

Interventions

A BP monitor cuff was placed on the arm contralateral to the diluted norepinephrine infusion, adjusted to the patient morphology. Baseline BP was defined as the first noninvasive measurement obtained after the patient was installed on the angiography table, on arrival in the angiosuite. The reference MAP was defined by the mean of the first 2 MAP measurements taken at 1-minute intervals, provided they did not differ by more than 10 mm Hg. Otherwise, a third measurement was performed, and the reference MAP was the mean of all 3

values (eSAP 1). For generalizability, BP was measured noninvasively, every 2.5 minutes. In line with the individualized design of the trial, no predefined BP threshold was required for randomization. This decision was based on prior observational data showing that intraprocedural BP variability and MAP deviations of ±10% from the value at groin puncture were independently associated with worse outcomes, regardless of baseline BP values.¹⁹

In the individualized BP group, the target was to maintain a MAP within 10% of the reference MAP, regardless of its absolute level. In this group, no upper limit for the corresponding SBP was imposed. This approach was based on the hypothesis that each patient's initial BP, measured immediately on arrival in the angiosuite, likely reflects the pressure required to preserve cerebral perfusion in the context of an acute LVO, particularly given the imminent administration of sedative agents known to induce hypotension. BP control was achieved using intravenous diluted norepinephrine (5 or 10 µg/mL) to prevent BP variability and treat hypotension (<10% below reference MAP),^{17,22–24} and intravenous nicardipine or urapidil for hypertension (>10% above reference MAP). Norepinephrine was administered continuously (i.e., no boluses) and initiated systematically before any sedation initiation to prevent hypotension (eSAP 1).

Patients in the standard BP group were managed according to current guidelines, primarily targeting hypertension (SBP <180 mm Hg and DBP <105 mm Hg),^{2,12} with hypotension addressed only if SBP dropped below 140 mm Hg, per recommendations of the Society for Neuroscience in Anesthesiology and Critical Care.²⁵ No pharmacologic intervention was applied if BP remained within these target ranges (i.e., no BP variability control). In cases of hypotension, physician could use norepinephrine (5–10 µg/mL), ephedrine (3 mg/mL), or phenylephrine (50 µg/mL), at their discretion. Hypertension could be treated with nicardipine or urapidil. Sedation modality was standardized for the trial (eSAP 1). All acute phase treatments followed current guidelines.

The intervention was considered complete on achieving successful reperfusion (modified Treatment in Cerebral Ischemia [mTICI] grade of 2b or 3) or on femoral artery closure if MT was unsuccessful (mTICI <2b). Neurologic evaluations were performed at admission, 24 hours, and 90 days.

Outcomes

The primary outcome was a favorable FO at 90 days (±15 days), defined as an mRS score of 0–2, assessed by certified neurologists or research nurses blinded to trial-group assignments, who had performed more than 30 mRS assessments, including at least 20 supervised by a senior professional with experience of more than 100 mRS evaluations. Secondary outcomes included the ordinal mRS score at 90 days, excellent FO at 90 days (mRS 0–1), early neurologic improvement at 24 hours (defined as an NIHSS reduction ≥8

points or an NIHSS of 0–1 24 hours after MT), successful reperfusion (mTICI 2b–3), final infarct volume at 24-hour post-MT (to be reported in a separate study), hospital stay duration, quality of hemodynamic control, BP variability (coefficient of variation), and time spent within the individualized MAP target ($\pm 10\%$ of reference MAP) during MT. Additional outcome definitions are provided in the protocol (eSAP 1). Safety outcomes included symptomatic intracranial hemorrhage on imaging between 22 and 36 hours, according to both the *European Cooperative Acute Stroke Study* (ECASS) III²⁶ and the *Safe Implementation of Thrombolysis in Stroke-Monitoring Study* (SITS-MOST)²⁷ definitions, and all-cause mortality at 90 days.

Sample Size Calculation

The expected rate of poor FO at 90 days in the control group was estimated at 54%.⁴ Based on recent observational data, the effect size of BP control within $\pm 10\%$ of the reference

MAP was anticipated to yield a relative risk of 0.7.¹⁹ Using a more conservative relative risk estimate of 0.75, an alpha level of 5%, and an interim efficacy analysis after 50% of inclusions according to an O'Brien-Fleming alpha spending approach, a total sample size of 432 randomized patients was calculated to provide 80% power (eSAP 2).

Statistical Analysis

Baseline characteristics and periprocedural BP variations were reported as numbers and percentages for categorical variables, and as means and SD or medians and interquartile ranges (IQR) for continuous variables, depending on their distribution. The primary and secondary binary outcomes (including excellent FO, early neurologic improvement, mortality at 90 days, symptomatic intracranial hemorrhage, and successful reperfusion after MT) were analyzed using a generalized linear mixed model with a Bernoulli distribution. This model included the intervention and stratification factors

Figure 1 Study Flow Chart

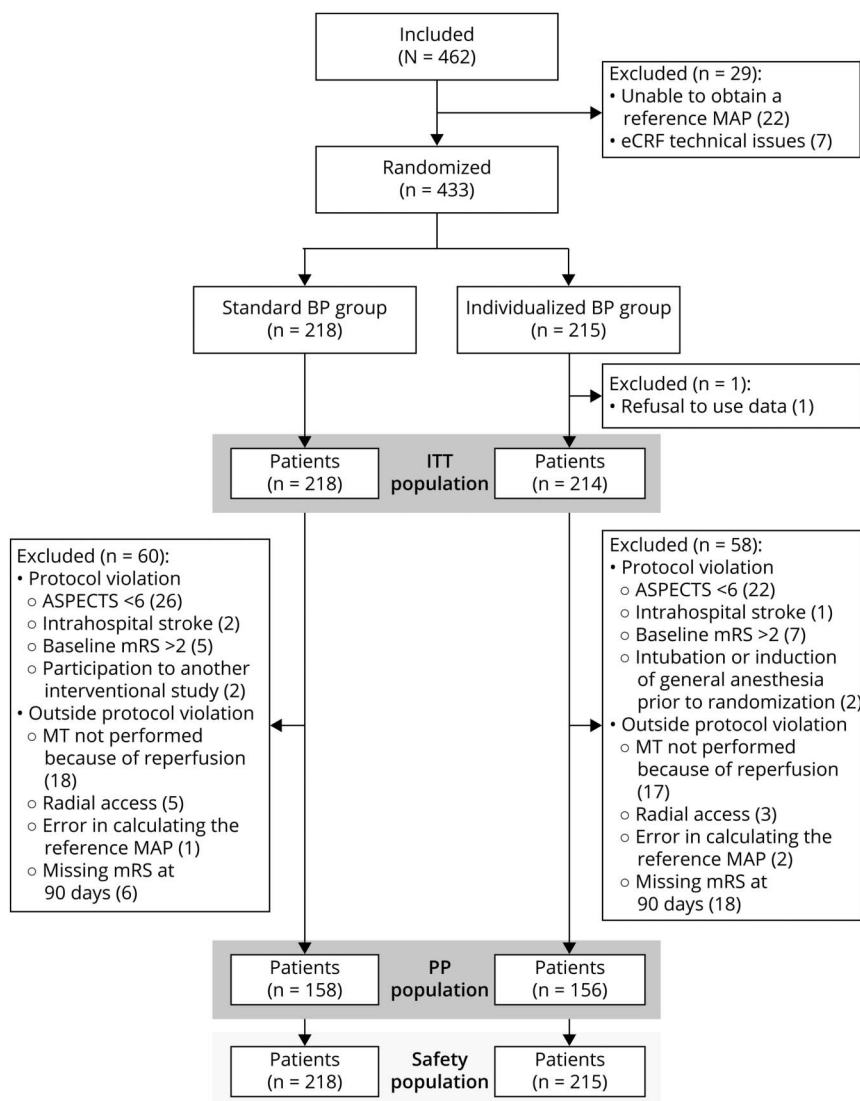


Table 1 Demographic and Clinical Characteristics of the Patients at Baseline

	Individualized BP group (N = 214)	Standard BP group (N = 218)
Age, y	69.1 (15)	69.6 (15.1)
Female sex, no. (%)	111/214 (51.9%)	117/218 (53.7%)
Hypertension	130/214 (61.9%)	133/218 (61%)
Diabetes mellitus	29/209 (13.9%)	33/218 (15.1%)
Dyslipidemia	65/209 (31.1%)	60/217 (27.6%)
History of ischemic stroke	27/210 (12.9%)	27/218 (12.4%)
History of myocardial infarction	9/209 (4.3%)	17/218 (7.8%)
Pre stroke mRS score >2 ^a	6/214 (2.8%)	5/218 (2.3%)
Directly admitted to a CSC	78/214 (36.4%)	77/218 (35.3%)
Antihypertensive treatments at admission	127/211 (60.2%)	124/218 (56.9%)
Antiplatelet therapy at admission	50/211 (23.7%)	50/218 (22.9%)
Anticoagulant therapy at admission	38/211 (18%)	30/218 (13.8%)
Median NIHSS score (IQR) ^b	15 (11–19)	15 (10–19)
Median ASPECTS (IQR)	8 (7–9)	8 (7–9)
Use of intravenous thrombolysis	121/213 (56.8%)	126/218 (57.8%)
Location of intracranial occlusion		
Intracranial ICA	32/213 (15%)	15/217 (6.9%)
M1	125/213 (58.7%)	112/217 (51.6%)
Proximal M2	40/213 (18.8%)	46/217 (21.2%)
Tandem lesion ^c	15/213 (7%)	28/217 (12.9%)
A1	1/213 (0.5%)	2/217 (0.9%)
Sedation modality		
Conscious sedation	194/212 (91.5%)	199/218 (91.3%)
General anesthesia	15/212 (7.1%)	13/218 (6%)
Conversion (CS to GA)	3/212 (1.4%)	6/218 (2.8%)
Median duration (IQR) (min)		
From onset to groin puncture (min) ^d	346 (245–630)	311 (227–468)
From onset to randomization (min) ^e	344 (244–608)	306 (220–459)
From onset to reperfusion (min) ^f	388 (289–588)	368 (274–560)
From puncture to reperfusion ^g	34.2 (22–50)	36 (21–55)
Mean systolic BP at admission	149.1 (24.9)	146.9 (24.2)
Mean diastolic BP at admission	83.1 (16.1)	83.1 (16.5)

Abbreviations: A1 = first segment of the anterior cerebral artery; ASPECTS = Alberta Stroke Program Early CT Score; BP = blood pressure; CS = conscious sedation; CSC = comprehensive stroke; GA = general anesthesia; ICA = internal carotid artery; IQR = interquartile range; M1 = first segment of the middle cerebral artery; mRS = modified Rankin Scale; NIHSS = National Institutes of Health Stroke Scale; proximal M2 = proximal portion of the second segment of the middle cerebral artery.

n/N (%) or mean (standard deviation) or median (interquartile range). Percentages may not total 100 because of rounding.

^aScores on the mRS range from 0 to 6, with higher scores indicating greater disability and 6 indicating death. Favorable functional outcome was defined as an mRS between 0 and 2 at 90 d.

^bScores on the NIHSS range from 0 (no symptoms) to 42 (most severe deficits).

^cTandem lesions were defined as an intracranial occlusion with an ipsilateral extracranial occlusion.

^dData were missing for 23 patients in the standard BP group and 22 in the individualized BP group.

^eData were missing for 22 patients in the standard BP group and 20 in the individualized BP group.

^fData were missing for 44 patients in the standard BP group and 39 in the individualized BP group.

^gData were missing for 45 patients in the standard BP group and 40 in the individualized BP group.

Table 2 Hemodynamic Parameters

	Individualized BP (N = 214)	Standard BP (N = 218)	Difference (95% CI) ^a
Baseline SBP	153.4 (30)	153.3 (27.7)	0.1 (−5.7 to 5.4)
Baseline MAP^b	107.9 (18.9)	108 (19)	−0.1 (−3.6 to 3.6)
Mean intraprocedural SBP^c	147.2 (25)	146.4 (20.1)	0.8 (−3.6 to 5.1)
Mean intraprocedural MAP^d	101.5 (16.8)	100 (14.8)	1.5 (−1.6 to 4.5)
Number of BP measurements per patient	16 (10 to 24)	15 (9 to 25.8)	1 (−3 to 2)
Incidence of SBP >180 or DBP >105 mm Hg	86/210 (41%)	84/217 (38.7%)	2.3 (−7.0 to 11.5)
Percentage of time spent with SBP >180 or DBP >105 mm Hg^e	0 (0 to 13.5)	0 (0 to 11.5)	0 (0 to 0)
Incidence of SBP <140 mm Hg	154/210 (73.3%)	160/217 (73.7%)	−0.4 (−8.8 to 7.8)
Percentage of time spent with SBP <140 mm Hg^f	38.8 (0 to 79.7)	32.1 (0 to 75)	6.7 (−11.9 to 21.5)
Percentage of time spent within normal BP target	43.2 (8.5 to 74.2)	53.1 (20.9 to 81)	−9.8 (−20.6 to 3.5)
Incidence of MAP >10% of baseline MAP	91/210 (43.3%)	83/212 (39.2%)	4.1 (−5.2 to 13.6)
Percentage of time spent with MAP >10% of baseline MAP^g	0 (0 to 8.7)	0 (0 to 6.6)	0 (0 to 0)
Incidence of MAP <10% of baseline MAP	166/210 (79%)	174/212 (82.1%)	−3.0 (−10.6 to 4.5)
Percentage of time spent with MAP <10% of baseline MAP^h	28.8 (7.3 to 59.2)	33.3 (9.8 to 66.7)	−4.6 (−14.9 to 4.5)
Percentage of time spent within ±10% of baseline MAP	58.1 (32.5 to 83.3)	53.7 (27.2 to 76.6)	4.4 (−5.5 to 15.2)
Coefficient of variation of SBPⁱ	7.6 (5.5 to 10.3)	7.6 (5.6 to 11.1)	0.0 (−1.0 to 1.0)
Coefficient of variation of MAP^j	7.7 (5.5 to 10.8)	7.8 (5.9 to 11.1)	−0.1 (−1.1 to 0.8)
AUC under baseline MAP (mm Hg×min)	267.4 (90 to 534.4)	306.2 (104.1 to 688)	−38.8 (−123.0 to 41.9)
ΔMAP	19 (12 to 27 · 8)	19 (12 to 29.2)	0 (−131.5 to 40.4)

Abbreviations: AUC = area under curve; BP = blood pressure; DBP = diastolic blood pressure; MAP = mean arterial pressure; SBP = systolic blood pressure; ΔMAP = difference between baseline MAP and lowest MAP during EVT.

^aThe 95% confidence intervals for the difference between medians were calculated using the bootstrap method, and the difference between means was calculated using the Student test.

^bReference MAP.

^cData were missing for 1 patient in the standard group and 4 patients in the individualized group.

^dData were missing for 6 patients in the standard group and 4 patients in the individualized group.

^eData were missing for 9 patients in the standard group and 5 patients in the individualized group.

^fData were missing for 4 patients in the standard group and 8 patients in the individualized group.

^gData were missing for 16 patients in the standard group and 10 patients in the individualized group.

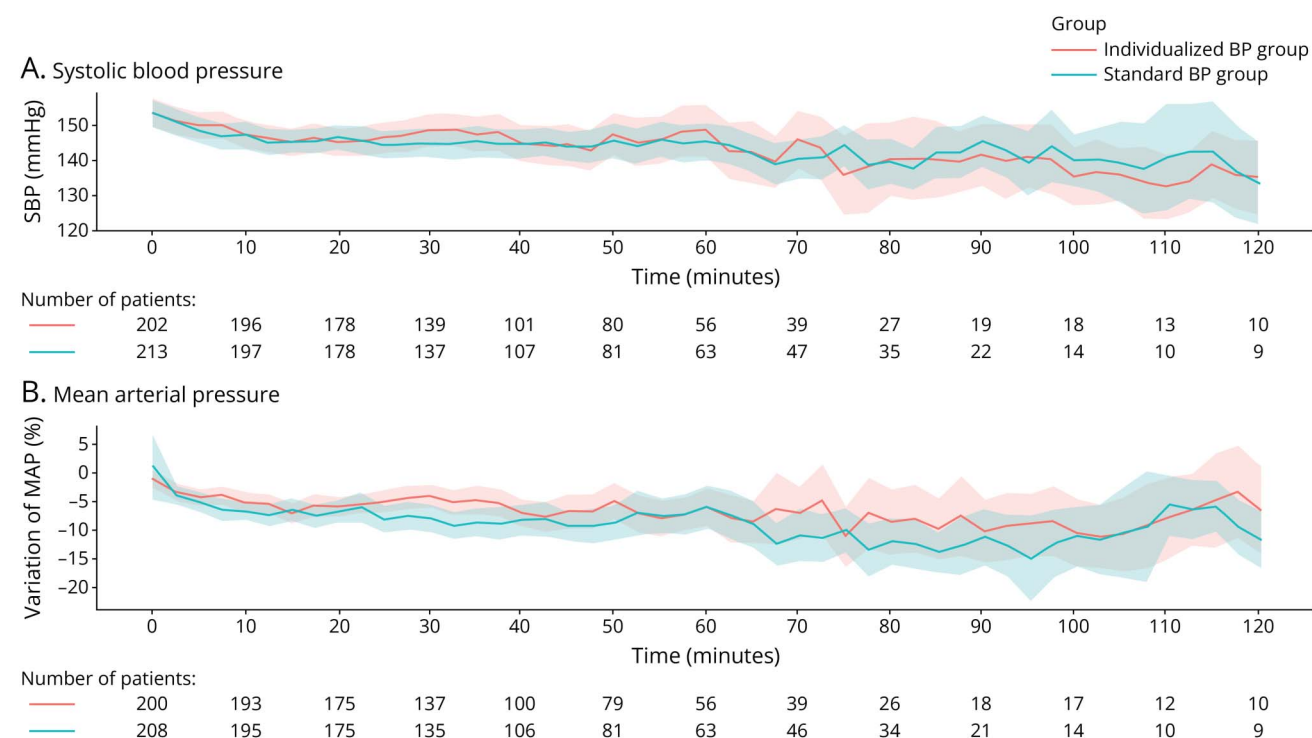
^hData were missing for 8 patients in the standard group and 4 patients in the individualized group.

ⁱData were missing for 2 patients in the standard group and 4 patients in the individualized group.

^jData were missing for 7 patients in the standard group and 4 patients in the individualized group.

(age, sedation modality, baseline NIHSS score, and intravenous thrombolysis) as fixed effects, and center as a random effect. Symptomatic intracranial hemorrhage using the SITS-MOST definition was analyzed without adjustment for stratification factors and center because of the limited number of events. Ordinal analysis of the mRS score at 90 days was performed using a mixed ordinal logistic regression model, adjusted for stratification factors as fixed effects and center as a random effect. The number of rehospitalizations was assessed using a generalized linear mixed model with a negative binomial distribution, including the intervention and stratification factors as fixed effects and center as a random effect. The duration of hospital stays and periprocedural BP variations were described for each group. Periprocedural BP variations were compared between groups using differences in proportions or differences in means or medians with 95%

confidence intervals. A predefined subgroup analysis was conducted to assess the primary outcome within categories of age, time from onset to treatment, history of hypertension, baseline NIHSS score, sex, sedation modality, intravenous thrombolysis, occlusion site, baseline SBP and MAP, and by center. For the primary outcome, missing data were managed through multiple imputations by chained equations in R software. Ten imputed data sets were generated, and prediction models were built for each. Parameter estimates were combined according to Rubin rules. Other missing data for other outcomes were not imputed. For the primary outcome analysis, a *p* value <0.049 was considered statistically significant. The primary analysis was conducted on the intention-to-treat population, with sensitivity analyses performed on one per-protocol population (all randomized patients who underwent MT without major protocol deviations/violations or

Figure 2 Systolic and Mean Arterial Blood Pressure in the Individualized and Standard Groups Over the Intervention Period

(A) Systolic blood pressure over the intervention and (B) percentage of variation of MAP compared with reference MAP over the intervention. BP = blood pressure; MAP = mean arterial pressure; SBP = stabilize systolic BP.

missing data for the primary outcome). All statistical analyses were performed using RStudio software (R version 4.4.1).

Data Availability

Deidentified participant data, including the complete CRF-derived study database, may be made available on reasonable request to qualified investigators, subject to steering committee approval and completion of a data transfer agreement.

Results

Characteristics of the Patients

From March 2021 to September 2023, 433 patients were randomized across 8 academic centers in France (distribution shown in eTable 1). Owing to nearly simultaneous enrollment (within 12 hours), the last patient was randomized just before the randomization website closed. After exclusion of 1 patient who withdrew consent, 432 patients were analyzed: 218 in the individualized group and 214 in the control group (Figure 1). Overall, 24 were lost to follow-up (5.5%).

A total of 19 protocol violations occurred (Figure 1), 3 patients with an intrahospital acute ischemic stroke were randomized, 12 patients had a baseline mRS >2 , 2 patients were intubated before randomization, and 2 participated to another interventional study. Overall, 35 patients did not undergo MT because of prior recanalization.

The baseline characteristics were similar (Table 1): median age was 69.3 years, 52.8% of the patients were women, and 61.4% had a history of hypertension. The median NIHSS score was 15 (10–19), and MT was performed under CS in 91.4% of cases.

Hemodynamic Management During MT

Mean (SD) intraprocedural MAP and SBP were 101.2 (17) and 146.9 (25.1) mm Hg in the individualized group, and 99.6 (14.8) and 146 (20.1) mm Hg in the control group. According to the individualized BP group definition, median (IQR) percentage of time spent within the BP target range during MT was 58.1% (32.5–83.3) in the individualized group and 53.7% (27.2–76.6) in the control group. Based on the control group definition, median (IQR) percentage of time spent within the BP target during MT was 43.2% (8.5–74.2) and 53.1% (20.9–81) in the individualized and control groups, respectively. The median (IQR) percentage of time spent with hypotension during MT, defined according to each BP target randomization group, was 28.8% (7.3–59.2) in the individualized group and 32.1% (0–75) in the control group. Further BP results are available in Table 2, Figure 2, and eTable 2. Vasopressors and antihypertensive used during MT are provided in eTable 3.

Primary Outcome

In the primary efficacy analysis, favorable FO (mRS between 0 and 2 at 90 days) was observed in 94 patients (44.2%) in the

Table 3 Primary and Secondary Outcomes

	Individualized BP group (N = 214)	Standard BP group (N = 218)	Odds ratio (95% CI)	Adjusted odds ratio ^a (95% CI)
Primary outcome				
Favorable functional outcome at 90 d (mRS 0–2)^b	94/214 (44.2)	106/218 (48.8)	0.83 (0.56 to 1.23)	0.82 (0.54 to 1.24)
Secondary outcomes				
Median mRS score at 90 d (IQR)^c	4 (2 to 6)	4 (2 to 5)	0.84 (0.59 to 1.18)	0.84 (0.59 to 1.18)
Excellent functional outcome at 90 d (mRS 0–1)	56/197 (28.4)	66/212 (31.1)	0.88 (0.57 to 1.34)	0.87 (0.56 to 1.35)
Early neurologic improvement at H24^d	74/197 (37.6)	73/200 (36.5)	1.05 (0.70 to 1.57)	1.05 (0.69 to 1.57)
Symptomatic intracranial hemorrhage (ECASS III)^e	16/203 (7.9)	14/203 (6.9)	1.16 (0.55 to 2.46)	1.17 (0.55 to 2.47)
Symptomatic intracranial hemorrhage (SITSMOST)^f	4/206 (2.4)	5/210 (2.4)	0.81 (0.20 to 3.11)	Not estimated ^g
Reperfusion at the end of MT^h	187/214 (87.4)	189/218 (86.7)	1.06 (0.61 to 1.87)	1.10 (0.62 to 1.95)
All-cause mortality at 90 d	37/197 (18.8)	35/213 (16.4)	1.18 (0.71 to 1.96)	1.19 (0.70 to 2.03)

Abbreviations: BP = blood pressure; IQR = interquartile range; mRS = modified Rankin Scale; MT = mechanical thrombectomy; mTICI = modified Treatment in Cerebral Ischemia; NIHSS = National Institutes of Health Stroke Scale.

^aEffect sizes are adjusted for prognostic factors used in the randomization procedure (age [<70 vs ≥ 70 y], sedation modality [conscious sedation vs general anesthesia], baseline NIHSS score [<17 vs ≥ 17], use of intravenous thrombolysis [yes vs no] as fixed effects, and center as a random effect. Secondary outcomes were not adjusted for multiple comparisons. Results are provided with n/N (%), with the % of patients who met the outcome.

^bMissing values on the modified Rankin scale were handled with multiple imputations.

^cScores of 5 and 6 on the modified Rankin scale scores were combined into one score in this analysis. Data were missing for 17 patients in the individualized group and 6 patients in the standard group.

^dEarly neurologic improvement at 24 h was defined as an NIHSS reduction ≥ 8 points or an NIHSS of 0–1 24 h after MT.

^eSymptomatic intracranial hemorrhage according to the European Cooperative Acute Stroke Study (ECASS) III was defined as any hemorrhage with neurologic deterioration, indicated by an NIHSS score ≥ 4 points above baseline, with hemorrhage identified as the primary cause.

^fSymptomatic intracranial hemorrhage according to the Safe Implementation of Thrombolysis in Stroke-Monitoring Study (SITS-MOST) criteria was defined as local or remote parenchymal hematoma type 2 on imaging between 22 and 36 h after treatment, with neurologic deterioration defined as an NIHSS score ≥ 4 points above baseline or leading to death.

^gThe effect size for the symptomatic intracranial hemorrhage according to the SITSMOST definition is provided without adjustment because of a low number of events.

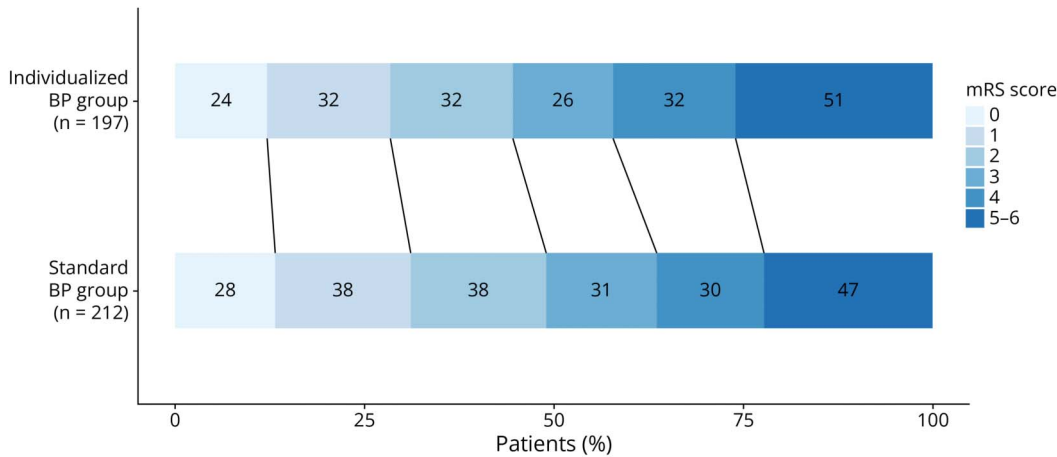
^hSuccessful reperfusion was defined as an mTICI 2b–3.

individualized groups and 106 patients (48.8%) in the control (adjusted odds ratio [OR], 0.82; 95% CI, 0.54–1.24; $p = 0.34$, Table 3, Figure 3). These results indicate that an individualized BP management during MT was not superior to standard BP management in improving FO at 90 days.

Secondary Outcomes

The median mRS score at 90 days was 4 (2–6) in the individualized group and 4 (2–5) in the control group; the adjusted OR for a shift in the score on the mRS at 90 days comparing the individualized BP group with the control

Figure 3 Modified Rankin Scale Score Distribution at 90 Days in the Overall Cohort



The mRS score measures the disability at 90 days and ranges from 0 to 6 (0, no symptoms; 1, no clinically significant disability; 2, slight disability; 3, moderate disability; 4, moderately severe disability; 5, severe disability; 6, death). BP = blood pressure; mRS = modified Rankin Scale.

group was 0.84 (95% CI 0.59–1.18), Figure 3, Table 3. An excellent FO (mRS between 0 and 1 at 90 days) was achieved in 56 patients (28.4%) in the individualized groups and 66 patients (31.1%) in the control group (adjusted OR, 0.87; 95% CI 0.56–1.35). Further secondary outcomes are presented in Table 3 and eTable 4.

Safety Outcomes and Adverse Events

Mortality from any cause at 90 days was 18.8% in the individualized group vs 16.4% in the control group: adjusted OR, 1.19; 95% CI 0.70–2.03, Table 3. Symptomatic intracranial hemorrhage occurred in 7.9% of the patients in the individualized group and 6.9% in the control group (adjusted OR, 1.17; 95% CI 0.55–2.47), according to the ECASS III definition, and in 2.4% and 2.4%, respectively (OR, 0.81; 95% CI 0.20–3.11), according to the SITS-MOST definition. Serious adverse events are detailed in eTable 5.

Sensitivity, Subgroup, and Post Hoc Analysis

Sensitivity analysis in the per-protocol population yielded similar findings (eTables 6 and 7). No significant interactions were observed in any of the prespecified subgroup about the primary outcome (eFigure 1). Post hoc analyses examining associations between the magnitude (Δ MAP), duration (area under the curve) of BP deviations, and time spent within BP targets with clinical outcomes are provided in eTables 8–11.

Classification of Evidence

This study provides Class II evidence that in patients undergoing mechanical thrombectomy for stroke due to anterior LVO, functional outcomes at 90 days were similar with individualized BP management and standard BP management.

Discussion

In this multicenter, open-label, randomized clinical trial, individualized BP management during MT (MAP within 10% of baseline MAP) was not associated with improved FO at 90 days compared with the control group (SBP 140–180 mm Hg), and no safety concerns were observed.

An individualized BP management during surgery, designed to avoid hypotension and minimize BP variability, has previously been evaluated in general surgery in the INPRESS trial and demonstrated its superiority over a one-size-fits-all approach.¹⁷ Consistent with our findings, INPRESS also reported only minimal differences in intraprocedural BP values between groups, a finding that was expected because the 2 groups had different BP management strategies at inclusion. However, in the INPRESS trial, systolic BP was consistently higher in the individualized group, and this difference was accompanied by substantially greater vasopressor exposure, in both frequency and dose, highlighting a clearer physiologic separation between groups than in the present trial. Beyond these differences, and more fundamentally, the hypothesized benefit of individualization lies less in absolute between-group

BP differences, as in conventional one-size-fits-all BP trials (i.e., where 2 different fixed BP targets are compared), than in improving BP variability control and tailoring targets to each patient's physiology. As such, hemodynamic trajectories resulting from these 2 strategies may diverge in clinically meaningful ways that are not adequately captured by simple comparisons of average intraprocedural BP values. Therefore, the absence of between-group BP differences likely reflects both the limited separation achieved between strategies and the challenges of implementing individualized BP control in the acute stroke setting. Indeed, the implementation of such strategy in the setting of AIS seems more challenging than in elective surgery. The recent INDIVIDUATE trial,¹⁸ which evaluated the efficacy of an individualized BP management during MT by maintaining SBP within a 10 mm Hg range, also failed to show superiority over standard management. Similarly, the IDEAL trial also did not show the superiority of an individualized BP management over the standard approach, particularly in patients predominantly treated with MT under general anesthesia.²⁰

Despite strong pathophysiologic rationale, one key factor likely explaining DETERMINE's neutral results is the challenge of maintaining narrow BP targets in real-world conditions. In this trial, half of the patients randomized in the individualized BP group spent 58% of their procedural time within the prescribed BP target. This difficulty is particularly noteworthy given that the DETERMINE, INDIVIDUATE, and IDEAL trials were conducted in high-volume stroke centers with dedicated neuroanesthesiology teams. Yet, despite this expertise, the coefficient of variation was similar across groups. This observation may reflect intrinsic limits of the titration protocol rather than protocol violations. In DETERMINE, BP was monitored noninvasively every 2.5 minutes. Although this frequency was higher than in previous trials, it still created intervals during which BP variations could go undetected, thereby favoring a reactive rather than a proactive approach to BP control. Furthermore, the protocol was derived from elective surgery and may not fully account for the hemodynamic instability seen in AIS, where sympathetic activation is heightened. Although a more aggressive titration strategy could have been considered, its implementation would have required invasive monitoring, and increased vasopressor exposure, raising ethical concerns. Nevertheless, this result does not challenge the broader concept of BP individualization per se but underscores the need to rethink its implementation. Future trials will likely require real-time, multimodal monitoring strategies (continuous intra-arterial BP measurement, near-infrared spectroscopy, and individualized autoregulation assessment), to tailor BP targets dynamically to each patient's physiologic state.^{28,29}

Current guidelines differ regarding the appropriate lower BP threshold to achieve during MT. North-American and European guidelines do not specify a lower BP threshold (<180/105 mm Hg),^{2,12} but the *Society of Neuroscience in Anesthesiology and Critical Care Expert Consensus Statement*

recommends a lower limit of 140 mm Hg during MT.²⁵ This threshold, which was also used in the control arms of the INDIVIDUATE and IDEAL trials,^{18,20} may provide adequate BP control during MT, while minimizing BP variability, and could serve as a reference for future trials. However, we cannot rule out a potential contamination bias that could explain the satisfactory BP management in the control group because the same investigators were responsible for both the individualized and control groups and may have improved BP control in the control group.

This trial has limitations. First, antihypertensive treatments between hospital admission and angiosuite arrival were not systematically recorded. As a result, we cannot assess the potential influence of admission BP management on subsequent outcomes. This reflects real-world stroke pathways in France, where some interhospital transfers lack medical supervision. Although admission BP may better reflect the patient's cerebral perfusion before sedation, our protocol was designed to initiate BP control on angiosuite arrival to ensure logistical feasibility across centers. It is important that randomization should have balanced any prerandomization hemodynamic variations between groups. Second, intermittent noninvasive BP monitoring may have contributed to undetected fluctuations and reactive adjustment. Future trials should consider integrating continuous monitoring methods (e.g., arterial lines and advanced noninvasive sensors) to enable more dynamic and precise BP control during MT. Third, the academic centers participating in this trial were high-volume stroke centers with a dedicated neuroanesthesiology team for each MT, which may limit generalizability. However, the proportion of patients achieving functional independence at 90 days in both the individualized and control groups (48.8%) was similar to those observed in trials and large observational registries where patients were treated without any dedicated anesthesiology team,³⁰ suggesting that the unavailability of the anesthesiology team should not restrict access to MT. Fourth, conscious sedation was used in 90% of cases, and additional trials are needed in patients treated under general anesthesia, given its higher risk of hypotension. However, the pilot IDEAL trial, which exclusively enrolled patients treated under general anesthesia, failed to meet the feasibility criteria for conducting such a trial.²⁰ Fifth, similar to the INPRESS trial,¹⁷ norepinephrine was the primary vasopressor used to control BP. As preclinical data have shown some potential paradoxical deleterious effect of norepinephrine in some patients,³¹ we cannot rule out that any potential benefit of the individualized BP management was attenuated by the use of this treatment. Finally, the absence of screening logs precludes a detailed assessment of potentially eligible but non-enrolled patients and could have introduced selection bias.

In conclusion, an individualized BP management (MAP within 10% of the first MAP) during MT was not superior to a standard BP control (SBP between 140 and 180 mm Hg) about FO at 90 days in patients suffering from an acute ischemic stroke due to an anterior large vessel occlusion.

Author Byline (Continued)

Erwan Robichon,² Simon Escalard,² Jean-Philippe Desilles,^{2,3,4,5} Stanislas Smajda,² Hocine Redjem,² William Boisseau,² Amira Al Raaisi,² Raphael Blanc,² Michel Piotin,² Pierre Seners,²² François Delvoe,² Pierre-Olivier Comby,²³ Perrine Boursin,² Amélie Yavchitz,²⁴ Céline Nekrouf,²⁴ Chloé Le Cossec,²⁴ Mikael Mazighi,^{2,3,4,5,25,*} Etienne Gayat,^{26,27,*} for the DETERMINE Investigators

Affiliation

¹Neurology Department, Hôpital Paris Saint-Joseph, France; ²Interventional Neuroradiology Department, Hôpital Fondation A. de Rothschild, Paris, France; ³INSERM, U1144, Paris, France; ⁴Université Paris Cité, France; ⁵FHU Neurovasc 2030, Paris, France; ⁶Department of Diagnostic and Therapeutic Neuroradiology, Université de Lorraine, CHRU-Nancy, France; ⁷Université de Lorraine, INSERM 1254, IAD, Nancy, France; ⁸Department of Anesthesia, Critical Care and Peri-Operative Medicine, Centre Hospitalier Universitaire de Clermont-Ferrand, France; ⁹Department of Anesthesia and Critical Care, University Hospital, Lille, France; ¹⁰Université Lille, ULR 2694 – METRICS, France; ¹¹Department of Anesthesia, Critical Care and Peri-Operative Medicine, APHP, Sorbonne Université, Hôpital Pitié-Salpêtrière, Paris, France; ¹²INSERM UMR 1141, Paris, France; ¹³Department of Neurological Anesthesiology and Intensive Care, Hospices Civils de Lyon, Hôpital Pierre Wertheimer, Groupement Hospitalier Est, Bron, France; ¹⁴Lyon's Neuroscience Research Center, INSERM U1028/CNRS UMR 5292, Lyon 1 University, France; ¹⁵Anesthesiology and Critical Care Department, University Hospital of Toulouse, University Toulouse 3-Paul Sabatier, France; ¹⁶Anesthesiology Department, Foch Hospital, Suresnes, France; ¹⁷Anesthesiology Department, Hôpital Fondation A. de Rothschild, Paris, France; ¹⁸Neurology Department, Stroke Unit, Foch Hospital, Suresnes, France; ¹⁹Interventional Neuroradiology Department, Hospices Civils de Lyon, Hôpital Pierre Wertheimer, Groupement Hospitalier Est, Bron, France; ²⁰Neurology Department, University Hospital of Toulouse, France; ²¹Anesthesiology Department, CHRU Nancy, France; ²²Neurology Department, Hôpital Fondation A. de Rothschild, Paris, France; ²³Department of Neuroradiology and Emergency Radiology, François-Mitterrand University Hospital, Dijon, France; ²⁴Clinical Research Unit, Hôpital Fondation A. de Rothschild, Paris, France; ²⁵Neurology Department, Hôpital Lariboisière, Paris, Institut Universitaire de France; ²⁶Université Paris Cité, AP-HP, Hôpital Lariboisière, DMU PAR-ABOL, Service d'Anesthésie-Réanimation-CTB, France; and ²⁷InsERM U942 MASCOT, Paris, France.

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Author Contributions

B. Maier: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data; study concept or design; analysis or interpretation of data. B. Gory: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data. R. Chabanne: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data; analysis or interpretation of data. B. Tavernier: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data; analysis or interpretation of data. A. Jacquens: major role in the acquisition of data. B. Balanca: major role in the acquisition of data. M. Pommier: major role in the acquisition of data. M. Le Guen: major role in the acquisition of data. L.-A. Thion: major role in the acquisition of data. S. Clariot: major role in the acquisition of data. B. Lapergue: major role in the

acquisition of data. A. Guyot: major role in the acquisition of data. O.F. Eker: major role in the acquisition of data. L. Bapteste: major role in the acquisition of data. J.M. Olivot: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data. L. Calviere: major role in the acquisition of data. G. Julean: major role in the acquisition of data. P. Bourst: major role in the acquisition of data. G. Audibert: major role in the acquisition of data. V. Degos: major role in the acquisition of data. J. Dupont: major role in the acquisition of data. E. Robichon: major role in the acquisition of data. S. Escalard: major role in the acquisition of data. J.-P. Desilles: major role in the acquisition of data. S. Smajda: major role in the acquisition of data. H. Redjem: major role in the acquisition of data. W. Boisseau: major role in the acquisition of data. A. Al Raaisi: major role in the acquisition of data. R. Blanc: major role in the acquisition of data. M. Pötin: major role in the acquisition of data. P. Seners: major role in the acquisition of data. F. Delvoye: major role in the acquisition of data. P.-O. Comby: major role in the acquisition of data. P. Boursin: major role in the acquisition of data. A. Yavchitz: major role in the acquisition of data. C. Nekrouf: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data; analysis or interpretation of data. C. Le Cossec: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data; study concept or design; analysis or interpretation of data. M. Mazighi: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data; study concept or design; analysis or interpretation of data. E. Gayat: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data; study concept or design; analysis or interpretation of data.

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Appendix Coinvestigators

Coinvestigators are listed in the Supplementary Material at [Neurology.org/N](https://www.neurology.org/N).

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